K121625

SEP 14 2012

Premarket Notification 510(k) Summary
As required by section 807.92

Lullaby™ Warmer

GENERAL COMPANY INFORMATION as required by 807.92(a)(1)

Date:	[10th May 2012]
Submitter:	Wipro GE Healthcare Private Ltd. 4, kadugodi industrial area bangalore, INDIA 560067
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Device: Trade Name:	Lullaby™ Warmer
Common/Usual Name:	Infant Radiant Warmer
Classification Names:	Warmer, Infant Radiant, Class : II
Product Code:	FMT , General Hospital and Personal use Theraputic Devices
Regulation No:	21 CFR 880.5130
Predicate Device(s):	Ohmeda Ohio® Infant Warmer System (K963058)

Device Description:	The Lullaby™ Warmer is a radiant warmer which provides a micro-environment for a premature, new born baby which otherwise might have very little chance of survival as it will not be able to maintain, by itself, its core body temperature. The Lullaby™ Warmer provides a means for the care giver to monitor the baby continuously by giving timely feedback via the different alarm systems and servo controlled thermal feedback mechanism while maintaining a pre-set temperature and thus ensures that the neonate slowly develops the internal organs to enable it to maintain its body temperature.

Indication for Use:	Infant radiant warmers provide infrared heat in a controlled manner to infants who are unable to maintain thermoregulation based on their own physiology. Infant radiant warmers may be used to facilitate the newborn's transition to the external environment or to provide a controlled open microenvironment.
Technology:	Lullaby™ Warmer uses the same fundamental technology as its predicate Ohmeda Ohio® Infant Warmer System providing radiant heat in a controlled manner to infants who are unable to maintain thermoregulation based on their own physiology. The control system uses a microprocessor and provides both manual and servo modes of operation. The patient temperature, control temperature, Apgar timer, Audio and visual alarm system are included on the control panel. The intended use for both predicate and the proposed device is the same only minor word phrasing differences are there in order to add more clarity. The Lullaby™ Warmer uses recliner mechanism for bed tilting which offers a wider tilting angle as compared to the predicate device. For more on the predicate device comparison refer to section 12 of this 510k submission.

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Determination of Substantial Equivalence:	Summary of Non-Clinical Tests: Verification and Testing activities establish the performance, functionality, usability, safety, and reliability characteristics of Lullaby™ Warmer. The Lullaby™ Warmer comply with voluntary standards as detailed in Section 09, 15, 16, 17 and 18 of this premarket submission. The following quality assurance measures were applied to the development of the system: • Risk Analysis • Requirements Reviews • Design Reviews Summary of Simulated Use Setting: The Design verification of Lullaby™ Warmer has been divided into several protocols that include electrical, mechanical, safety Testing, reliability, and system design verification protocols. The performance testing included testing on unit level, system level, as well as usability and safety parameters. The results of the Design verification testing protocols have been documented in Section 18 of this 510(k) application. The results demonstrate that the Lullaby™ Warmer meets all design requirements and performance claims. The subject of this premarket submission, Lullaby™ Warmer , did not require clinical studies to support substantial equivalence.
Conclusion:	GE Healthcare considers the Lullaby™ Warmer to be as safe and as effective as the predicate device, and the performance to be substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Wipro GE Healthcare Private Ltd.
C/O Ms. Agata Anthony
Regulatory Affairs Director
GE Healthcare
8880 Gorman Road
Laurel, Maryland 20723

SEP 14 2012

Re: K121625
Trade/Device Name: Lullaby™ Warmer
Regulation Number: 21 CFR 880.5130
Regulation Name: Infant Radiant Warmer
Regulatory Class: II
Product Code: FMT
Dated: August 14, 2012
Received: August 20, 2012

Dear Ms. Anthony:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121625

Device Name: Lullaby™ Warmer

Indications for Use:

Infant radiant Warmers provide infrared heat in a controlled manner to infants who are unable to maintain thermoregulation based on their own physiology. Infant radiant Warmers may be used to facilitate the newborn's transition to the external environment or to provide a controlled open microenvironment.

Prescription Use ☒ AND/OR Over-The-Counter Use _

(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Richard Chapman

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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